

Applicants : BERMUDEZ, et al.  
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REMARKS

Applicants have amended the value "1.7" in Table 2B on page 45, line 18, of the specification, back to the *original* and correct value of "17". The previous amendment of this value was in error and inadvertent. Applicants respectfully request that Examiner enter this amendment.

Applicants have canceled claims 45, 48, 50, 51, 54, 56, and 59 without prejudice to Applicants' right to subsequently pursue the canceled subject matter in this or a future application. Applicants have also amended claims 44, 46, 47, 49, 52, 53, 55, 57, 61, and 62 to better reflect the *Salmonella* strains in Example 6 of the originally-filed specification.

Amended claim 44 is based on canceled claims 48, 54, and 56. Claim 46 was amended to properly depend on claim 44 in view of the cancellation of claim 45. Claim 47 was amended in view of the incorporation of the subject matter of canceled claim 48 into claim 44. Claim 49 was amended to particularly point out and distinctly claim the subject matter of the present invention by removing the language, "derived from the strain." Amended claim 52 is based on canceled claims 40-43. Support for amended claim 53 may be found on page 45, line 18, of the originally-filed specification. Support for amended claim 55 may be found on page 47, lines 10 and 13-15, of the originally-filed specification. Support for amended claim 57 may be found on page 21, line 8, of the originally-filed specification. Amended claim 61 is based on currently amended claim 44 and originally-filed claims 14 and 17. Amended claim 62 is based on currently amended claim 44 and originally-filed claim 9.

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35 U.S.C. 112, 1<sup>st</sup> Paragraph Rejection (Enablement)

The Examiner rejected claims 44-48, 50-58, and 60-62 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, on grounds that "the specification, while enabling for particular tumor targeting Salmonella strains, and a method of using said strain, does not reasonably provide enablement for [any] tumor-targeting Salmonella strain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims." In conclusion, the Examiner states that "it would clearly require undue experimentation by one of [ordinary] skill in the art to determine how to make the claimed strains and kits, and use the claimed method comprising administering tumor targeting Salmonella strains other than those shown in the specification to specifically deliver filamentous phage to tumor cells, in Example 6."

In response, Applicants still adhere to their previous arguments, filed on September 16, 2005 (see pages 7-13 of September 16, 2005 response), although said arguments have not been reproduced herein for purposes of brevity. However, in the interest of furthering the prosecution of the present application and without conceding the correctness of the Examiner's position, Applicants have amended the appropriate claims to focus on the Salmonella strains disclosed in Example 6 of the specification.

The Examiner also rejected claims 49, 50, and 59 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, on grounds of failing to comply with the enablement requirement since the claims refer to biological

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material, and "[i]t is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public."

In response, Applicants note that the proper deposit information regarding the biological material in claim 49 may be found on page 10, lines 16-21, and on page 42, line 24, of the originally-filed specification. Deposit information may also be found on page 28, lines 11-13; page 36, lines 12, 14, 24, and 31; page 40, lines 26, 29, and 30; page 45, lines 21-22; and page 45.2 of cross-referenced International Publication No. WO 99/13053. Deposit information may additionally be found on page 139, line 16; page 146; and page 147, line 7, of cross-referenced International Publication No. WO 96/40238. Please note that the designation "strain 72" is interchangeable with the designation "YS72" in claim 49.

Regarding claims 50 and 59, the rejection is moot in view of the cancellation of the claims.

Accordingly, Applicants respectfully request Examiner to withdraw the above grounds of rejection.

**35 U.S.C. 112, 1<sup>st</sup> Paragraph Rejection (Written Description)**

The Examiner rejected claims 44-48, 50-58, and 60-62 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, on grounds of "failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In conclusion, the Examiner states that "only the particular tumor targeting Salmonella of Example 6, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph."

In response, Applicants still adhere to their previous arguments, filed on September 16, 2005 (see pages 16-17 of the September 16, 2005 response), although said arguments have not been reproduced herein for purposes of brevity. However, in the interest of furthering the prosecution of the present application and without conceding the correctness of the Examiner's position, Applicants have amended the appropriate claims to focus on the Salmonella strains disclosed in Example 6 of the specification.

The Examiner also rejected claim 49 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, on grounds of new matter. In particular, the Examiner states that "[t]he specification as originally filed does not provide support for the invention as now claimed: 'the group consisting of YS72 (ATCC Accession No. 55680)'."

In response, Applicants would like to note that the designation "strain 72," mentioned on page 42, line 24, of the originally-filed specification, is interchangeable with the designation "YS72" in claim 49. For example, the originally-filed specification cross-references a number of publications, including International Publication Nos. 99/13053 (cross-referenced on page 10, line 17, and page 44, line 28, of the

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originally-filed specification) and 96/40238 (cross-referenced on page 42, line 24, of the originally-filed specification). WO 96/40238 refers to "YS72" as "Clone #72" and "strain #72" (see page 139, line 16, and page 147, line 7, of WO 96/40238) in its disclosure. WO 99/13053 also refers to "YS72" as well as WO 96/40238 (see page 28, lines 11-13, and page 36, line 31, of WO 99/13053). Although the designation "YS72" is preferred, Applicants are willing to change the designation to "strain 72" if Examiner so instructs.

Accordingly, Applicants respectfully request the Examiner to withdraw the above ground of rejection.

35 U.S.C. 112, 2<sup>nd</sup> Paragraph Rejection

The Examiner rejected claims 49 and 59 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, on grounds of being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular, the Examiner states that "[c]laims 49, and by dependence, claim 59, are vague and indefinite in the recitation of 'the Salmonella typhimurium is derived from . . . ' since the number and types of steps involved in said deriving are not known, and therefore it cannot be determined what the intended metes and bounds of the claimed subject matter are."

In response, Applicants have amended claim 49 to remove the offending language, "derived from the strain." Regarding claim 59, the rejection is moot in view of the cancellation of the claim.

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Accordingly, Applicants respectfully request the Examiner to withdraw the above ground of rejection.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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